

1043-19

12-01-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DEC 1 2009

Michael G. Sarli
Lead Regulatory Specialist
Steris Corp.
P.O. Box 147
St. Louis, MO 63166-0647

Subject: Notification in Accordance with PR Notice 98-10
Staphene Disinfectant Spray & Deodorizer
EPA Registration No. 1043-19
Application Date: November 5, 2009
Receipt Date: November 9, 2009

Dear Mr. Sarli:

This acknowledges receipt of your application, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

Label change due to PR Notice 2007-4
Notification of additional influenza A virus per PR Notice 95-2

General Comments

Based on a review of the material submitted, the following comments apply:

The notification is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6427 or email address at: Carlisle.shaRon@epa.gov or Renae Whitaker by telephone at (703) 308-7003 or email at whitaker.renae@epa.gov during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

ShaRon Carlisle
(Acting) Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

EPA	United States Environmental Protection Agency Washington, DC 20460	Registration Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 1043-19	2. EPA Product Manager ShaRon Carlisle	3. Proposed Classification
4. Company/Product (Name) Staphene Disinfectant Spray & Deodorizer	PM # 34	<input checked="" type="checkbox"/> None <input checked="" type="checkbox"/> Restricted
5. Name and Address of Applicant (include Zip Code) STERIS Corp. P.O. Box 147 St. Louis, MO 63166-0647 Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name	

Section - II

Amendment - Explain below. Resubmission in response to Agency letter dated <input checked="" type="checkbox"/> Notification - Explain below.	Final printed labels in response to Agency letter dated "Me Too" Applicaton Other - Explain below.
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Explanation: Notification of label change per PR Notice 2007-4 and Notification of Additional Influenza A virus per PR Notice 95-2.

This notification is consistent with the guidance in PR Notice 2007-4, PR Notice 95-2 and the requirements of EPA's regulations at 40 CFR §§ 152.46, 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 152.46, 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product will be Packaged In:					
Child-Resistant Packaging Yes* <input checked="" type="checkbox"/> No	Unit Packaging Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal Plastic Glass Paper Other (Specify)		
*Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 16 oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Michael G. Sarli	Title Lead Regulatory Specialist	Telephone No. (Include Area Code) 314-290-4704			
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 	3. Title Lead Regulatory Specialist				
4. Typed Name Michael G. Sarli	5. Date 11/05/09				

STERIS®



November 5, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
Regulatory Management Branch 1
Antimicrobials Division (7510C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
Attn: ShaRon Carlisle, PM #34

Re: Notification for Staphene® Disinfectant Spray & Deodorizer (EPA Reg. No. 1043-19)
Revision of Container Disposal Language in Compliance with PR Notice 2007-4
Addition of H1N1 Influenza Virus in Compliance with PR Notice 95-2

Dear Ms. Carlisle:

Enclosed in support of the subject action, please find the following:

- Application for Pesticide (EPA Form 8570-1)
- Labeling (1 copy) - Changes described with comments
- Labeling (1 copy) - "Clean" copy

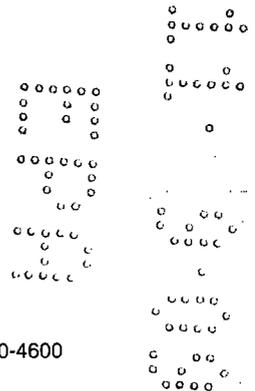
The Container Disposal statement has been revised in compliance with PR Notice 9007-4. The language related to the H1N1 Influenza A virus is drawn verbatim from the "Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)" EPA publication.

If you have any questions I can be reached at 314-290-4704 or at mike_sarli@steris.com.

Sincerely,

Michael G. Sarli
Lead Regulatory Specialist
STERIS Corporation

Enclosures



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Staphene®

DISINFECTANT SPRAY AND DEODORIZER

Germicidal, Tuberculocidal, Air Deodorizer, Fungicidal, Virucidal*

ACTIVE INGREDIENTS

o-benzyl-p-chlorphenol	0.077%
p-tertiary amyphenol	0.074%
o-phenylphenol	0.041%
N-alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethylbenzyl ammonium chlorides	0.042%
N-alkyl (50% C ₁₂ , 30% C ₁₄ , 17% C ₁₆ , 3% C ₁₈) dimethyl ethylbenzyl ammonium chlorides	0.042%
ethanol	53.096%
INERT INGREDIENTS	46.628%
TOTAL	100.000%

NOTIFICATION
 Date Reviewed: 12/1/09
 Reviewed By: K. Whitaker

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If inhaled	<ul style="list-style-type: none"> •Move person to fresh air. •If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. •Call a poison control center or doctor for further treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> •Take off contaminated clothing. •Rinse skin immediately with plenty of water for 15-20 minutes. •Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none"> •Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. •Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none"> •Call poison control center or doctor immediately for treatment advice. •Have person sip a glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

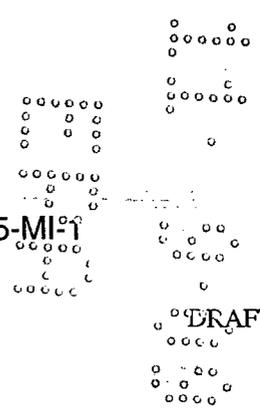
See side panel for additional precautionary statements

Net Contents 16 oz. (1 lb.) (453g)

STERIS

7501 Page Ave.
St. Louis, Mo 63133

EPA Reg. No. 1043-19 EPA Est. No. 33915-MI-1



DRAFT 11-4-09

**PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS**

CAUTION: Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing before reuse. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

PHYSICAL AND CHEMICAL HAZARDS

Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperature above 130°F may cause bursting. Never throw container into incinerator.

Staphene Disinfectant Spray and Deodorizer is an aerosol-dispensed, spot disinfectant and deodorant for schools, medical, dental and business offices, homes, sick rooms, nursing homes and general hospital use.

- Bedside and office furniture •Trash carts •Telephones •Waste cans and laundry hampers •Sinks

Germicidal: Passes A.O.A.C. Germicidal Spray Products Test (Staphylococcus aureus, Salmonella enterica, Pseudomonas aeruginosa) in the presence of 5% blood serum, 10 minutes at 20°C.

Tuberculocidal: Passes A.O.A.C. Germicidal Spray Products Test (Mycobacterium tuberculosis var.bovis) in the presence of 5% blood serum, 10 minutes at room temperature (25°C/77°F) on hard inanimate surfaces. Gross filth or heavy soils must be removed before disinfection.

Fungicidal: Passes A.O.A.C. Germicidal Spray Products Test (Trichophyton mentagrophytes) in the presence of 5% blood serum, 10 minutes at 20°C.

***Virucidal:** Passes virucidal assay (EPA Proposed Method) [Influenza A, Herpes simplex Type 2, Rhinovirus Type 1A] in the presence of 5% blood serum, 10 minutes at 20°C on hard inanimate surfaces.

When tested by an EPA-approved Dilution Method, the HIV-1 (AIDS) virus, with added 10% organic soil (serum), was completely inactivated in 60 seconds at 20-25°C. Although efficacy at 1 minute contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Use a 10-minute contact time for disinfection against all of the organisms claimed.

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

or

Kills Pandemic 2009 H1N1 influenza A virus formerly called swine flu.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Following application as a spray, do not enter or allow others to enter the treated area until sprays have dried. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application.

General and Tuberculous Disinfection, Elimination of Fungi and Viruses*; Spray hard, non-porous environmental surfaces from any angle, even upside down, from a distance of 6-8 inches for 2-3 seconds or until surface is thoroughly wet. Allow surfaces to remain wet for 10 minutes or allow to air dry without wiping or rinsing. Gross filth or heavy soils must be removed before disinfection.

